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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,922	07/05/2001	Klaus Kramer	51568	1797

26474 7590 09/27/2002

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1350 CONNECTICUT AVENUE, N.W.
WASHINGTON, DC 20036

EXAMINER

LAMBKIN, DEBORAH C

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 09/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

1-6, 11

12
14
15

Office Action Summary

Application No.

09/897,922

Applicant(s)

KRAMER ET AL.

Examiner

Deborah C Lambkin

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other:

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6, 11-12 and 14-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. "Use" by itself is non-statutory.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"A preparation" is somewhat vague since it is not clear exactly what it includes or excludes beyond a composition.

It is suggested that applicant use the conventional language of "A composition".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-10 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Garnett (US 5,463,093).

Garnett teaches palladium complexes of lipoic acid which read on the instant "mineral salt" and "metal complex" of lipoic acid.

Claims 7-10 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Hettche et al (5,990,152).

Hettche et al teaches alkali or alkaline earth metal complexes of alpha-lipoic acid and its isomers which read on the instant "mineral salt" and "metal complex" of lipoic acid (col.1, lines 35-45; col.2, lines 50-55 and ex.2).

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(a) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 7-10 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Pearson et al (US 6,288,106).

Pearson et al teach Mg, Cu and Zn complexes of alpha-lipoic acid which read on the instant "mineral salt" and "metal complex" of lipoic acid (see examples 1-12).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7-10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hettche et al, Pearson et al or Bingham et al (US 6,331,559) each alone or in view of Garnett.

Hettche et al and Pearson et al have been discussed supra, furthermore they both teach that mineral salts or metal complexes of lipoic acid and its isomers are conventional formulations in the art.

Bingham et al teach non-palladium metal chelates of lipoic acid (col.6, lines 1-68).

The above references do not teach the equivalence of lipoic acid and its reduced form, dihydrolipoic acid.

Garnett teaches this equivalence in metal complexes of lipoic acid (col.8, lines 60-65).

It would have been prima facie obvious to one having ordinary skill in the art at the time the application was filed to, on the one hand, choose a species from a prior art genus, in this case, any one of the listed metal salts from the genus of Hettche et al, Pearson et al and Bingham et al, and expect them to possess the same or similar properties as their exemplified counterparts, and on the other hand to make said metal salts of dihydrolipoic acid because lipoic acid and dihydrolipoic acid are taught to be equivalents in the art by Garnett, with a reasonable expectation that the resultant metal complexes would possess the same or similar properties as their known counterparts, absent some unobvious or unexpected results.

No unobvious or unexpected results are seen.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah C. Lambkin whose telephone number is 703-308-4522.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached on (703) 308-4537. The fax phone number for the organization where this application or proceeding is assigned is 703-308-7922.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Deborah C. Lambkin
Primary Patent Examiner
Art Unit 1626